IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** ***WAVE 1 CASES***	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN OPINIONS OF ALAN GARELY, M.D.

COME NOW, Plaintiffs and file their Response in Opposition to Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Defendants") Motion to Exclude Certain Opinions of Alan Garely, M.D., and show as follows:

INTRODUCTION AND DR. GARELY'S QUALIFICATIONS

A copy of Dr. Garely's Curriculum Vitae is attached hereto as **Exhibit 1**. Dr. Garely is Board Certified in both Obstetrics and Gynecology and Female Pelvic Medicine and Reconstructive Surgery (FPRMS). He is currently the Chair of the Department of Obstetrics and Gynecology (2012 to present) and Director of Urogynecology and Pelvic Reconstructive Surgery (2009 to present) at South Nassau Communities Hospital in Oceanside, New York. He is also an Associate Professor of Clinical Obstetrics, Gynecology and Reproductive Science at Mount Sinai School of Medicine in New York (2009 to present).

He holds an MD from Saint George's University School of Medicine, and he did his internship and residency in Obstetrics and Gynecology at the Saint Vincent's Hospital

and Medical Center in New York City. Dr. Garely completed his two-year fellowship in Urogynecology and Pelvic Reconstructive Surgery in June 1995.

Dr. Garely was an Assistant Professor of Obstetrics and Gynecology at LSU Medical Center until June 1995 until October 1997. From October 1997 until May 2002, he was the Associate Director of Urogynecology and Pelvic Reconstructive Surgery at North Shore University Hospital, as well as an Assistant Professor of Obstetrics and Gynecology at New York University School of Medicine. After leaving North Shore, Dr. Garely became the Vice-Chair of Obstetrics and Gynecology, Chief of Gynecology, and Director of Urogynecology and Pelvic Reconstructive Surgery at Winthrop University Hospital on Long Island and he also served as an Associate Professor of Obstetrics and Gynecology at the State University of New York, Stony Brook.

Dr. Garely remains active in the accredited fellowship program in Female Pelvic Medicine and Reconstructive Surgery at Mount Sinai and he teaches medical students, residents and fellows every week. As his Curriculum Vitae reflects, Dr. Garely has trained more than 15 post-doctoral fellows in Female Pelvic Medicine and Reconstructive Surgery.

Dr. Garely is a member of the American Urogynecologic Society (AUGS) and served on its Board of Directors from 2006-2009 and was the Director of the AUGS Government Relations Committee during that time. From 2000-2003, Dr. Garely served on the AUGS Public Relations Committee. He is currently the AUGS representative to the American College of Surgeons (ACS), and is in his second term on the ACS Obstetrics and Gynecology Advisory Board. Dr. Garely is a fellow of both the American College of Obstetricians and Gynecologists (ACOG) and the American College of

Surgeons. Dr. Garely was awarded the Association of Professors of Gynecology and Obstetrics (APGO) "Excellence in Training" award in 2007, and was the AUGS-ACS Health Policy Scholar, also in 2007.

Dr. Garely has also been an Oral Board Examiner for the American Board of Obstetrics and Gynecology since 2010. In addition, Dr. Garely has served as a Journal Reviewer for the following peer-reviewed medical journals and publications: Obstetrics and Gynecology, International Urogynecology Journal and Pelvic Floor Dysfunction, Ob-Gyn Management, Nature (Clinical Practice Urology), American Journal of Managed Care, Journal of Reproductive Medicine, Expert Opinion on Emerging Drugs, Journal of the American College of Surgeons, and the Journal of Female Pelvic Medicine and Reconstructive Surgery.

Dr. Garely has authored several peer-reviewed articles, some of which are specific to pelvic repair mesh.[1] Along with several other prominent pelvic repair surgeons (including Ethicon Key Opinion Leader and Defendants' non-retained expert Vincent Lucente), Dr. Garely co-authored one of the first peer-reviewed articles discussing the use of mesh in treatment of stress urinary incontinence by United States

[1] The peer-reviewed journal articles authored or co-authored by Dr. Garely include the following: *The evolution of evaluation and management of urinary or fecal incontinence and pelvic organ prolapse*, Curr Probl Surg. 2015 Mar; 52(3):92-136; *Urogynecologic conditions: chronic pelvic pain*, FP Essent. 2015 Mar; 430:29-32; *Urogynecologic conditions: pelvic organ prolapse*, FP Essen. 2015 Mar: 430:23-8; *Mesh erosion following abdominal sacral colpopexy in the absence and presence of the cervical stump.* Int Urogynecol J. 2013 Jan; 24(1):113-8; *Magnetic resonance imaging of abdominal versus vaginal prolapse surgery with mesh.* Int Urogynecol J. 2012 Nov; 23(11):1569-76; *Minimally Invasive Approach to Pelvic Reconstructive Surgery*, J Min Invasive Gynecol 15(6): 75S; *MRI pelvic landmark angles in the assessment of apical pelvic organ prolapse.* Arch Gynecol Obstet. 2011 Aug;284(2):365-70; *Recognition of occult bladder injury during the tension-free vaginal tape procedure.* Obstet Gynecol. 2002 Jun;99(6):1067-72; *Paravaginal repair of lateral vaginal wall defects by fixation to the ischial periosteum and obturator membrane.* Am J Obstet Gynecol. 1998 Dec;179(6 Pt 1):1436-45; *Surgical landmarks of the ureter in the cadaveric female pelvis.* Clin Anat. 1997;10(5):324-7.

physicians, *Tension free vaginal tape (TVT) for the treatment of stress urinary incontinence: the initial North American experience*. Int Urogynecol J. Aug 1999 (suppl):S1-S914. This peer-reviewed journal article involved one of Defendants' pelvic repair mesh devices, the TVT sling. He is the first author of the "Clinical Expert Opinion Series on the Surgical Treatment of Stress Incontinence" published in the November 2014 of Obstetrics and Gynecology (The Green Journal), entitled *Diagnosis and Surgical Treatment of Stress Urinary Incontinence*. Obstet & Gynecol. 2014. 124(5):1011-1027. Dr. Garely has presented 38 papers and has given 88 lectures both nationally and internationally, including articles related specifically to the use of pelvic repair mesh. He has also written 4 book chapters on pelvic floor disorders.[2]

Dr. Garely's first experience with mesh used to treat pelvic floor defects was in 1998, when he trained on the Defendants' TVT SUI sling, at the Karolinska Institutet, in Sweden. (Garely Rule 26 Report, p. 5; *See also, Id.*, pp. 29-30). After returning from Sweden, he performed one of the first TVT operations in the United States. (*Id.*). Dr. Garely was an active preceptor and proctor for the Defendants on the TVT procedure until 2002. (*Id.*). Dr. Garely was a paid consultant for Ethicon, and he gave lectures for Ethicon on the TVT device at Ethicon-sponsored events. (*Id.*, pp. 29-30; *See also*, Garely CV (**Exhibit 1** hereto), pp. 19-20).

[2] The book chapters include: Rectal Prolapse, Current surgical Therapy, 2014, 11th Edition, Eds. JL Cameron and AM Cameron; Minimally invasive surgery for urinary incontinence. Chapter 12, Operative Gynecologic Laparoscopy: Principles and Techniques, 2008, Eds. F Nezhat and C Nezhat; Transabdominal procedures for the treatment of stress urinary incontinence; Chapter 8, Female Pelvic Health, 2002, Eds. Carlin and FC Leong; Repair of vesicovaginal, urethrovaginal and ureterovaginal fistulas. Section XV.

Dr. Garely also contributed to the monograph *Gynecare TVT with Abdominal Guides – Early Clinical Experience*, which Defendants themselves prepared and disseminated to surgeons for purposes of training and education with respect to their TVT device. (Garely depo., 129:9-131:22 (a copy of Dr. Garely's miniscript deposition is attached hereto as **Exhibit 2**)).

Dr. Garely explains that he was consulted by Ethicon to evaluate the TVM procedure (which ultimately was the procedure used in the Prolift and Prolift +M). (Garely Report, p. 30). He explains that when he offered his opinion to Ethicon's medical and corporate directors that the TVM procedure could not be taught to mainstream gynecology or urology surgeons without encountering large numbers of complications, he "was promptly dropped from Ethicon as a consultant." (*Id.*).

From 2003-2004, Dr. Garely was involved in the teaching and preceptoring for the Tyco IVS Tunneler, a mesh device used to treat pelvic organ prolapse. (Garely Report, p. 5).[3] Dr. Garely was also involved in the development of the IVS Tunneller, including participating in animal and cadaver lab studies. (Garely depo., 47:11-19). After 15 cases with the IVS Tunneller device, Dr. Garely abandoned its use secondary to a high rate of mesh erosions and failures. (Garely Report, p. 5).

Over the past 15 years, Dr. Garely has done consulting work for several medical device and pharmaceutical manufacturers, including US Surgical/Tyco, Covidien, Caldera, AMS, and Bard – and these Defendants. (Garely Report, pp. 5-6; *See also*, Garely CV, p. 3)). For example, Dr. Garely worked with AMS to develop the Interpro Y

[3] As reflected in his CV, Dr. Garely conducted several demonstrations and led roundtable discussions relating to the IVS Tunneller pelvic organ prolapse device, as well as courses relating to the Defendants' TVT device. (*See*, **Exhibit 1**, pp. 19-20; *See also*, Garely depo., 117:18-119:19).

mesh, and he participated in the evaluation and development of a surgical device by U.S. Surgical/Covidien used to clamp, cut and cauterize tissue, including consulting with researchers during laboratory testing of the device. (Garely Report, p. 6; *See also*, Garely depo., 42:5-19 (Garely explaining that he has experience in product development "from the drawing board to marketing."); *Id.*, 45:6-46:19 (discussing involvement in testing and analysis of clamping/cauterizing surgical device)). Dr. Garely also developed his own surgical approach in conjunction with Boston Scientific for sacrospinous mesh fixation for prolapse repair. (*Id.*, 48:3-23 and 78:4-79:1).

Dr. Garely testified that he has performed thousands of pelvic repair surgeries using synthetic mesh devices. (Garely depo., 70:11-21 and 72:16-19 (over 1,000 sacrocolpopexies using polypropylene mesh); 106:1-107:4 (1,500-2,000 SUI slings)). Of the many patients that he has treated over the years with mesh-related complications, Dr. Garely testified that he has explanted mesh that he knows to be Prolift or Gynemesh PS in between 10 and 20 patients, and he explained in detail on questioning by defense counsel his findings relating to these explants. (Garely depo., 141:11-142:9; 191:5-197:16)

ARGUMENT AND CITATION OF AUTHORITY

I. Dr. Garely does not purport to offer any opinion regarding Defendants' "knowledge, state of mind, and alleged bad acts."

Defendants' contention that any opinion set forth in Dr. Garely's Report could somehow be construed as an opinion regarding Defendants' state of mind is factually without support. The few quotations from Dr. Garely's Report recited in Defendants' Brief (Defendants' Brief, p. 3) are not "state of mind" opinions, but instead are Dr. Garely's citations to and summaries of the specific facts and evidence which Dr. Garely

reviewed and which form part of the basis for his opinions. Dr. Garely cites to specific documentation from published data or else from Defendants' own documents to support his reliance upon these facts as foundations for the opinions he offers.

Although Defendants criticize Dr. Garely's citation of several pertinent internal corporate documents that support his opinions (Defendants' Brief, p. 4), the documents referenced in Dr. Garely's Report speak to design defect and safer feasible alternative design, both of which are key issues in this case. The documents referenced in Dr. Garely's Report also bear directly on what information was available to Defendants regarding the safety and efficacy of the Prolift and Prolift +M, and in turn, what information Defendants included (or failed to include) in their labeling and marketing materials for these devices. Simply because Dr. Garely cites to a corporate document – which may reflect what information was available to Defendants and what they did in light of that information – to form his design and warnings opinions, does not mean he is offering impermissible "state of mind" opinions. Dr. Garely's discussion of Defendants' internal documents in his expert report falls squarely within the parameters previously recognized by this Court – that is, "an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible. . . ."[4] *See also*, *Wise*, 2015 WL 521202 at *13 ("[T]hough an expert may not simply narrate corporate documents in front of the jury, he may rely on such information in forming and supporting his opinions….").

[4] *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 610 (S.D.W.Va.2013).

In *Smith v. Pfizer*, 714 F.Supp.2d 845 (M.D.Tenn.2010), the Court denied a similar *Daubert* motion arguing that the plaintiff's expert had offered improper "state of mind/intent" opinions, stating as follows:

> [Plaintiff's expert] King may properly testify as to his interpretation of internal marketing-related documents that he relied on in forming his opinions. *See In re Seroquel Prods. Liab. Litig.*, No. 6:06–md–1769, 2009 WL 3806436, at *4 (M.D.Fla. July 20, 2009) (holding that expert witnesses may 'rely on and discuss [the defendant's] internal corporate documents.... To rule otherwise would unduly restrict Plaintiffs' experts from explaining the bases of their opinions.'). He may not, however, testify as to the defendants' motives or intent. *Id*. The defendants highlight instances of arguably objectionable portions of King's testimony in previous MDL cases. (*See* Docket No. 119 at 11, 11 n. 12.) But King's statement, which has been filed with the court and will constitute his direct testimony in this case, does not contain any speculation regarding the defendants' motives or intent. (*See* Docket No. 180, Ex. 6.) The court notes that the defendants may object at trial if they believe that King's testimony, outside of his statement, improperly discusses motive or intent.").[5]

Defendants' efforts to prevent Dr. Garely from citing to corporate documents – which form part of the basis of his opinions – by mischaracterizing his report and his testimony are unavailing. Consistent with the Court's prior rulings, Dr. Garely draws on the important facts of this case, including but not limited to Defendants' internal corporate documents, in order to support his opinion. Defendants' argument about "state of mind" opinions is misplaced.

II. Dr. Garely is well-qualified to offer opinions relating to the adequacy of Defendants' warnings and instructions for the Prolift and Prolift +M, and his warnings-related opinions are reliable.

In Section II of their Motion, Defendants argue that Dr. Garely is not qualified to render opinions relating to the adequacy of product warnings and his opinions are not

[5] *See also, In re Yasmin and Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625 (S.D.Ill.2011) (plaintiffs' OB-GYN experts were qualified to render risk-benefit and warning opinions based, in part, on review of internal corporate documents, and review of such materials – along with peer-reviewed literature – was a reliable methodology for rendering such opinions).

reliable. Specifically, Defendants contend that Dr. Garely is not an expert in warnings, and he is not qualified to opine about the FDA. These arguments are unfounded.

Dr. Garely's expertise in female pelvic health and reconstructive surgery generally, and the use of mesh in female pelvic surgery specifically, is beyond reasonable dispute. Dr. Garely explains that he has reviewed numerous Instructions for Use (IFU) for a variety of medical products, including mesh products, in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with the devices. (Garely Rule 26 Report, p. 6; *See also*, *Id.*, pp. 21, 28). Dr. Garely has reviewed the Prolift training and marketing materials, as well as the Prolift IFU. (*Id.*, p. 21 and p. 28).

Dr. Garely has been a practicing pelvic reconstructive surgeon and educator for 19 years. (*Id.*). As set forth above, Dr. Garely has not only used pelvic mesh products, he has proctored for and consulted with several mesh device manufacturers, including these Defendants, specifically with respect to their pelvic repair mesh products. (*Id.*). Dr. Garely has published extensively, including peer-reviewed articles relating to mesh specifically, and he serves as a peer-reviewer for several respected publications relating to female pelvic repair surgery. (*Id.*, pp. 3-4). Dr. Garely has taught hundreds of surgeons how to implant slings and female pelvic mesh products, including numerous physicians that he trained as a preceptor for these Defendants with respect to their pelvic repair mesh products. (*Id.*, p. 6; Garely depo., 117:18-119:19).

Dr. Garely's work with mesh manufacturers as an early user of these products, and as both a proctor and a consultant, provide him with the requisite expertise to offer opinions about the Defendants' products, including but not limited to the warnings and

instructions for those products. As discussed above, Dr. Garely was among the first wave of physicians in the country to use synthetic mesh in treatment of SUI (the Ethicon TVT) and of prolapse (the Tyco/Covidien IVS Tunneller). (Garely Report, pp. 5-6). Dr. Garely has consulted with several pelvic repair mesh manufacturers, and in fact, he was consulted by Defendants specifically with respect to development and evaluation of their pelvic repair mesh devices, and he has instructed numerous physicians in the use of Defendants' products. (*Id.*, p. 6; p. 9; pp. 29-30; **Exhibit 1** (Garely CV), pp. 3-4, 18-20; Garely depo., 42:5-19; 45:6-46:19; 47:11-19; 48:3-23; 78:4-79:1)). Dr. Garely explained on his deposition that he has advised companies in the formulation of their Instructions for Use for their devices. (Garely depo., 36:22-37:4). In fact, Dr. Garely testified that he was "intimately involved in formulating the IFUs to help instruct and educate physicians in the United States on how to use the [TVT] product" – Defendants' own device and IFU. (Garely depo., 36:22-38:18).

Based on his extensive qualifications and experience, as well as his review of the Defendants' IFUs and internal documents, Dr. Garely provides his opinions concerning the adequacy of the Prolift and Prolift +M warnings, and he explains the bases for those opinions in detail. In *Wise v. C.R. Bard, Inc.*, 2015 WL 521202, *14 (S.D.W.Va. 2015), the Court allowed plaintiffs' urogynecologist experts to opine as to the adequacy of the Defendants' product warnings in the face of a *Daubert* challenge similar to that asserted here, concluding that "as an experienced urogynecologist, [plaintiffs' expert] may testify about the risks he perceives that the [defendant's mesh] product poses to patients and then opine that the [product's] IFU did not convey those risks."); *See also, Id.*, p. *5 ("A

urogynecologist…is qualified to make this comparison [whether the product's risks were adequately conveyed in the IFU]."). A similar ruling is warranted here.

Defendants' contention that Dr. Garely is not a warnings expert, and is not an expert on FDA labeling regulations, is misplaced. As this Court explained in *Edwards v. Ethicon, Inc.*, "Dr. Blaivas [an expert urogynecologist] need not be an expert on product warnings per se. Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risk were adequately expressed on the TVT-O's IFU." *Edwards*, 2014 WL 3361923 at *13.

In *In re Yasmin and Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, *11-*13 (S.D.Ill.2011), the drug manufacturer defendant argued that the plaintiffs' proffered experts, both Obstetrician-Gynecologists, were not qualified to offer opinions regarding the adequacy of its labeling, in part because they had no FDA regulatory expertise. The court in *In re Yasmin* rejected this argument, and held instructively as follows:

> As a practicing OB/GYN tasked with making prescription decisions on a daily basis, Dr. Bercy-Roberson is qualified to opine as to how certain knowledge, obtained through studies, reports, and internal Bayer documents, would have affected her previous prescription-related decisions. Dr. Bercy-Roberson does not require expertise in FDA regulations to opine in this manner, as she does not comment on the conduct of the FDA. Further, doctors are 'fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs]…and to compare that knowledge with what was provided in the text of labeling and warnings for FDA approved drugs.' *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, *11 (E.D.Pa. June 20, 2000). Thus, Dr. Bercy-Roberson is qualfied to render an opinion as to the drug label's completeness and accurateness. *See id.*...

> Thus, as Dr. Bercy-Roberson's opinion based on peer-reviewed sources and data, her methodology is sound. The correctness of her opinion is left to the trier of fact's determination.[6]

As Dr. Garely explains in his Report, "[i]n order to make an informed decision as to whether to use a particular product in a given patient, a reasonable physician expects medical device sellers to provide all appropriate information known to the company that could impact that decision," and "[a] company's failure to disclose to a physician information relating to the potential safety of a product not only prevents the physician from being able to make an informed decision about the product," it "also prevents the physician from properly counseling patients considering whether to agree to implantation of the medical device." (Garely Prolift Report, p. 22). Dr. Garely's opinions regarding the completeness and accuracy of Defendants' IFU's are essential to this case and will aid the jury in evaluating the adequacy of the document that provides one basis for the physician's risk/benefit analysis and ultimately the information that is conveyed (or not conveyed) to the patient. *See Edwards*, 2014 WL 3361923 at *13. Defendants'

[6] The same holding with respect to the Plaintiffs other proffered OB-GYN expert in the *Yaz* MDL (Anthony Disciullo) – based on his extensive clinical experience and review of peer-reviewed literature and company documents, he was qualified to offer opinions as to the adequacy of the drug warning label, and his opinions were reliable. *See also Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F.Supp.2d 684, 702 (W.D.N.C. 2003) (citing *In re: Diet* Drug MDL PTO 1332, where the MDL court concluded physicians are "'qualified to render an opinion as to the labels' completeness, accuracy, and . . . the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits . . . are or were at the time the labeling was published.'…"); *Accord, Burton v. Wyeth-Ayerst Labs. Div. of Amer. Home Prods. Corp.*, 513 F.Supp.2d 708, 712 (N.D.Tex.2007); *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.2d 531, 556 (S.D.N.Y.2004) ("Pursuant to the defendants' concession [in light of *In re: Diet Drugs*], and subject to relevance rulings to be made by the trial courts, these [physician expert] witnesses are not precluded from offering otherwise admissible testimony as to the accuracy of the Rezulin label."); *In re Baycol Prods. Litig.*, 532 F.Supp.2d 1029, 1063-64 (D.Minn.2007) (citing *In re: Diet Drugs* opinion in denying defense *Daubert* motion to exclude physician expert opinion regarding drug labeling, stating "The Court agrees that [the plaintiffs' physician expert] is qualified to render an opinion regarding the completeness or accuracy of the Baycol label based on his knowledge of the risks of Baycol and his own clinical experience.").

challenges to Dr. Garely's opinions on warnings and information contained within the Prolift and Prolift +M IFU's should be denied.

Defendants' contention that "Dr. Garely makes blatantly false statements regarding Ethicon's dissemination of adverse events" (Defendants' Brief, p. 10) is questionable given that Dr. Garely cites to specific internal documents (often verbatim) in support of the very statements from his Report with which Defendants take issue. However, it is unnecessary here to debate with Defendants the veracity of any particular statement in Dr. Garely's Report; at best, that may present a subject for cross-examination at trial. Defendants essentially seek to challenge Dr. Garely's characterization of the information relied upon in support of his opinions, or else the accuracy of his conclusions based thereon, rather than the methodology that he employed in relying on such information to support his opinions. As such, Defendants' argument goes to the credibility, not the admissibility, of Dr. Garely's testimony in question. *In re St. Jude Medical, Inc. Silzone Heart Valves Prods. Liab. Litig.*, 493 F.Supp.2d 1082, 1089 (D.Minn.2007) ("As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination."); *In re: Digitek Prods. Liab. Litig.*, 821 F.Supp.2d 822, 837 (S.D.W.Va.2011) (the *Daubert* inquiry focuses solely on "the 'principles and methodology' employed by the expert, not on the conclusions reached.").

III. As addressed previously in this Response, Dr. Garely does not offer any "historical commentary."

In Section III of their Brief, Defendants merely rehash the same groundless argument asserted elsewhere in their Brief, that is that Dr. Garely cannot provide a

"factual narrative" or "commentary." Plaintiffs addressed this same argument in Section I above, and the same response applies here, as well. In the interests of brevity, Plaintiffs incorporate by reference their Response to Section I and the citation of authority and reasoning therein, as if restated here in its entirety. Again, Defendants cannot file a *Daubert* motion to prevent the jury from learning the facts that form the support for and basis of Dr. Garely's opinions.

IV. Dr. Garely has not offered any opinion related to FDA regulatory processes or requirements, and therefore, Defendants' argument to exclude any such opinions is misguided.

Contrary to Defendants' characterization, Dr. Garely has not offered any expert opinion regarding the FDA or its regulatory processes. Throughout the course of this litigation, Defendants have fought vehemently to be allowed to introduce evidence of the FDA's regulatory processes. The Court has correctly excluded such evidence to date in these cases. *See, e.g., In re C.R. Bard, Inc. MDL No. 2187 Pelvic Repair Sys. Prods. Liab. Litig.* (*Cisson v. C.R. Bard, Inc.*), 810 F.3d 913, 919-23 (4th Cir.2016) (evidence regarding 510(k) clearance and related FDA evidence of POP kit device properly excluded). As Plaintiffs have consistently shown, and the Court has repeatedly and properly held, this evidence has no place in this pelvic mesh litigation for a variety of reasons. However, in the event Defendants were allowed by any trial judge on remand to introduce any FDA-related evidence, they cannot simultaneously prevent the jury from learning the facts about the FDA regulatory history of the Prolift product. That Prolift was sold and implanted for years without 510(k) clearance or permission is not an opinion; it is an undeniable fact. These facts inform and support Dr. Garely's opinions regarding the adequacy of Defendants' warnings, and is the sort of information that

doctors and patients would expect to be told by a medical device seller. Likewise, the fact that the FDA has determined that the Prolift and Prolift +M devices have not been shown to be safe and effective, and that the products were removed from the market in response to an FDA 522 Order, are not matters of Dr. Garely's opinion, but are matters of fact. These facts bear directly on the risk/benefit design defect analysis, as well as several other issues and defenses the Defendants have indicated their intent to raise in these cases.

For example, as the Court is well aware, the pelvic mesh defendants in these MDLs (including these Defendants) have argued extensively that the FDA reviews a 510(k) device to determine its safety and efficacy, and therefore the FDA's 510(k) clearance of their products is at least "some evidence" that the products were safe and effective. That argument is meritless, as has been established. However, if that is the argument Defendants intend to make (and if they were to be allowed to do so), then surely the fact that Defendants knowingly circumvented this process in bringing the Prolift to market would be a permissible subject of expert testimony. Likewise, the fact that the FDA has, in fact, actually reviewed these products, and specifically concluded that there is no demonstrable evidence of safety or efficacy (and the products have been removed from the market as a result) is "fair game" for expert consideration. In short, if Defendants were successful in persuading any trial judge to allow in FDA evidence in any of these cases upon remand, Defendants cannot avoid the truth. The items addressed

in Defendants' motion are facts, not opinions; as such, Defendants' *Daubert* motion should be denied.[7]

V. Dr. Garely does not intend to offer any opinion about mesh degradation at trial.

Because Dr. Garely will not offer any opinion about mesh degradation, Section V of Defendants' Brief is moot.

VI. Defendants' contention that Dr. Garely cannot offer opinions regarding the complications associated with the Prolift and Prolift +M design, and the adequacy of Defendants' warnings related to these risks, because he is not a "biomaterials" expert should be rejected.

Defendants contention that Dr. Garely cannot offer opinions regarding the risks and complications associated with the Prolift and Prolift +M devices, and Defendants' failure to properly warn and advise physicians and patients about such risks, because he is not a biomaterials scientist disregards this Court's prior instructive rulings on this subject. This Court has ruled several times that familiarity with peer-reviewed, published literature, and experience in treating mesh complications, provides a sufficient basis upon which to offer an opinion regarding the in vivo behavior of mesh. *Edwards v. Ethicon, Inc.*, C.A. No. 2:12-cv-09972 (Dkt. No. 129, pp. 19-20) (citing prior opinion from *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872, at *20 (S.D. W. Va. Jan. 15, 2014) (holding that urogynecologist qualified to offer opinion regarding polypropylene characteristics and in vivo behavior based on having explanted multiple polypropylene mesh products, and review of applicable literature); *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, *5 (S.D.W.Va.2015) (citing

[7] This self-serving attempt to "have it both ways" is one of the main reasons this Court has excluded FDA regulatory evidence in the first instance, as the myriad risks associated with this evidence far outweigh any argued probative value, which is *de minimis*, at best.

prior decisions in concluding that defendant's contention that plaintiff's urogynecologist expert was not a "biomaterials expert" did not prevent design defect testimony which was based upon extensive clinical experience and review of literature).[8] Dr. Garely has extensive experience in both the implantation and surgical removal of pelvic repair mesh, and treatment of mesh-related complications, and he has also reviewed numerous internal corporate documents and dozens of peer-reviewed, published articles in forming his opinions regarding the design of the Prolift and Prolift +M. Moreover, as set forth above, Dr. Garely has consulted with several different medical device manufacturers regarding the development of pelvic repair mesh devices, including these Defendants regarding their TVT device and TVM procedure. Furthermore, as he explained at length in his deposition, Dr. Garely's opinions relating to the problematic features of the Prolift are based at least in part on his own clinical experience in removing Prolift mesh or Gynemesh PS from his own patients. (Garely depo., 187:15-198:5 (Dr. Garely explaining his own clinical experience and observations in removing Prolift mesh, and how they support his opinions related to the design of the Prolift product)).

[8] *See also, Bee v. Novartis Pharmaceuticals Corp.*, 18 F.Supp.3d 268, 303-04 (E.D.N.Y.2014) (despite drug manufacturer's *Daubert* challenge to plaintiff's retained physician expert's qualifications to offer general and specific causation opinions because it claimed he was not an expert in a variety of scientific sub-specialties, court held "[i]t is clear that if an expert has educational and experiential qualifications in a general field closely related to the subject matter in question, the court will not exclude [an expert's] testimony solely on the ground that the witness lacks expertise in the specialized areas that are directly pertinent…," and found that physician was qualified based on his "extensive, hands-on experience treating patients with forms of jaw necrosis," as well as his own research and familiarity with research of others); *In re Yasmin and Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, *7 and *9 (S.D.Ill.2011) (plaintiffs' Obstetrician-Gynecologist experts held qualified to offer opinions regarding safety of drug based upon "years of training and experience as an OB/GYN" and review of applicable published literature and internal company documents, and physician experts' methodology of reliance on literature and pertinent public documents was reliable); *See also, Id.* at *15-*17 (OB-GYN experts qualified to opine as to need for access to certain risk-benefit information, and opinions reliable as based on peer-reviewed publications and corporate documents).

Defendants contend in their Brief that "Dr. Garely's opinions on alleged nerve entrapment in mesh are a perfect example of where his opinions extend beyond his expertise." (Defendants' Brief, p. 15). To the contrary, Plaintiffs submit that this is instead a "perfect example" of why Defendants' argument should fail. Dr. Garely's opinions regarding the relationship between Defendants' pelvic mesh products and nerve injury – including nerve entrapment – are based not only on his knowledge, education, training and experience, but also on his review and familiarity with published literature addressing the association between polypropylene mesh implants and nerve damage, as well as several of Defendants' own internal documents – spanning several years – that expressly acknowledge the causal association between synthetic pelvic mesh implants and nerve injury. (*See, e.g.*, Garely Prolift Report, p. 11 ¶ 6 and footnote 19; *Id.*, p. 27 ¶ 10 and footnote 50).[9] *See also*, Garely Review Materials, served with his Expert Reports,

[9] The following documents and literature are cited in Dr. Garely's Reports: ETH.MESH.05631478 (8/16/02 internal Ethicon e-mail discussing article describing mesh-related nerve injury – ("In the post retrieval study most explants of all patients with chronic pain in their history indicate nerve fibres and fascicles in the interface of the mesh. Today, immunohistochemical stains relieve even the detection of smallest nerve structures which are mainly found in the foreign body granuloma. Due to the nature of the granuloma as a chronic inflammation it may be speculated that these nerve structures are irritated by the inflammation and cause the sensation of pain"); ETH.MESH.05455879 (1/18/03 notes from Ethicon Surgeon Panel Meeting) – "Nerve entrapment with chronic pain - Persistent chronic pain from foreign body reaction – greater fibrosis greater complaints – Scar plate with nerve entrapment – sometimes after one year there are no complaints and then complaints happen – often the result of tiny nerves in the granuloma not just a matter of not damaging the major nerves such as N ilioinguinalis or R genitalis - even if you care for the big nerves you can't prevent pain."); ETH.MESH.00870466 (6/20/06 notes re: Ethicon Expert Meeting) – "Meshes can cause Nerve damage due to mechanical irritation (mesh bears on nerve)…. Vaginal pain after implantation of meshes is rare, but feared, since there is not real treatment option"); HMESH_ETH_01800994 (10/11/06 internal Ethicon e-mail chain discussing mesh pain/shrinkage literature) ("The take home message from the article was that chronic pain can be associated with placement of a mesh device…. [The author] continues to point out that neuropathy-related complaints after intraoperative damage of nerve fibers is associated with pain immediately after surgery, however, the onset of chronic pain as a consequence of the 'foreign body reaction' is typically more than one year after the hernia repair. He goes on to point out that patients that reported chronic pain demonstrated nerve fibers and fascicles in the interface of the mesh upon examination upon removal."); HMESH_ETH_00144721 (2/11/08 internal e-mail) – "Peripheral nerve irritation

copy attached hereto as **Exhibit 3**).[10] Given that published literature and Defendants' own internal documents have acknowledged and discussed the direct causal link between pelvic mesh implants and nerve damage for years (including well before the Prolift devices were ever marketed), Defendants' challenge here to Dr. Garely's opinions regarding this issue is ill-founded.

VII. Defendants' challenge to Dr. Garely's safer alternative opinions is unfounded.

Defendants' criticism of Dr. Garely's opinions regarding feasible alternative features of the Prolift and Prolift +M designs that would have made the devices safer amounts to little more than a disagreement with his opinions. This is not a valid basis for a *Daubert* challenge.

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following synthetic mesh implantation can be implant-related or procedure-related. Implant-related factors include foreign body tissue reaction, fibrotic tissue response and shrinkage."); ETH.MESH.13375497 (10/1/08 internal PowerPoint) (Regarding mesh-related pain "The tissue reaction at the mesh implant is like a chronic wound, present for years and years after the implantation," and studies of explanted meshes show "Nerve fibers and fascicles in the interface of the mesh…The nerve structures are irritated by the inflammation an cause sensation of pain."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering."); ETH.MESH.05479695 (Nov. 3-4, 2010 Mesh and Textile Summit PowerPoint) – "Studies of explanted meshes: • Nerve fibers and fascicles in the interface of mesh • The nerve structures are irritated by the inflammation and cause sensation of pain [citing 2005 article].").

[10] Dr. Garely's Review Materials include hundreds of internal Ethicon documents related to the Prolift and Ethicon pelvic mesh products generally, as well as dozens of peer-reviewed, published articles specific to the Prolift product. In addition to the articles and internal documents directly referenced in his Report, several of these articles in his Review Materials discuss mesh-related nerve injury, including: Achtari C, et al. Anatomical study of the obturator foramen and dorsal nerve of the clitoris and their relationship to minimally invasive slings. Int Urogynecol J Pelvic Floor Dysfunct. 2006;17(4):330-4; Atassi Z, et al., Haemorrhage and nerve damage as complications of TVT-O procedure: case report and literature review. Arch Gynecol Obstet. 2008;277(2):161-4; Yi J, Pudendal nerve entrapment following posterior trans-vaginal mesh procedure cadaveric demonstration of pudendal nerve dissection. Pelv Med Reconstr Surg. 2012;18(8):S95. Video 16 at AUGS 2012; Masata J, et al., Pudendal neuralgia following transobturator inside-out tape procedure (TVT-O)--case report and anatomical study. Int Urogynecol J. 2012; 23(4):505-7.

For example, Ethicon challenges Dr. Garely's opinion that polyvinylidene fluoride (PVDF) was a safer feasible alternative material to polypropylene, pointing to Dr. Garely's testimony that he has not reviewed published literature relating to use of PVDF mesh as a prolapse treatment. (Defendants' Brief, p. 18). There is no such literature because there is no PVDF pelvic organ prolapse product (likely, Plaintiffs submit, because PVDF is more expensive than polypropylene). Dr. Garely cites to a volume of internal Ethicon corporate documents dating back decades that consistently recognize the safety advantages of PVDF, and specifically PVDF versus polypropylene. (Garely Prolift Report, p. 23 footnote 37 and footnote 39; Garely depo., 208:12-210:14 (discussing review of Defendants' internal documents as support for opinion related to PVDF as safer material)).[11] Likewise, Defendants' assertion that Dr. Garely's opinion

[11] HMESH_ETH_02860031 (7/06/07 internal e-mail from Ethicon Research Fellow regarding "dog" study) – "I recall the long-term dog study did show some 'fibrillation' of PROLENE suture where none was observed for PRONOVA [PVDF] suture. My polymer colleagues tell me that PP has the potential to do this because of its molecular structure."); HMESH_ETH_00228962 (2/17/10 internal e-mail chain discussing literature about polypropylene degradation) – "[W]e know from literature that polyester and even polypropylene tend to alter over time in the body…. [H]ow has the general surgery group responded to this [degradation literature]?...[W]e proposed for several new product developments...to use PVDF or PRONOVA as a more stable filament, however Senior Management decided to go ahead with PP as a standard."); ETH.MESH.14445346 (1/17/12 PowerPoint), Slide 11 (comparing Polypropylene to PVDF) – "PP – Stress cracking after 2 years of implantation [citing Mary article from 1998]… PP – In vivo degradation of PP [citing Clave article from 2009]."); ETH.MESH.09888188 (10/15/92 internal study report) – "Degradation in PROLENE is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking"; ETH.MESH.05644809 (8/2/01 internal notes) – "Advantages of Pronova • 50% reduced granuloma (Aachen group) • high inertness (like Teflon) • durability • reduced bending stiffness (better flexibility) • elasticity (fiber elasticity contributing 25% to mesh elasticity, rest by construction) • higher purity (only a blend)"; ETH.MESH.05588125 (7/6/07 internal email) – Dr. Dieter Engel: "Pronova has a reduced foreign body reaction compared to Prolene, as shown in several animal studies, and will improve the perceived biocompatibility of our mesh"; ETH.MESH.05878699 (9/13/07 internal study report) – Prof. Klosterhalfen: "Pronova [compared to Prolene] indicates a superior biocompatibility in the crucial early stage of wound healing within the first weeks"; ETH.MESH.15377374 (8/12/09 internal communication to a supplier) – "…PVDF polymers showed acceptable and often improved performance as compared to PP mesh devices. We have previously shared the preclinical biocompatibility studies for PRONOVA suture (report dated June 1998). Similar findings would be expected for a mesh device made

that a non-armed mesh would be safer is nothing but an "abstract notion" is non-sense. Non-armed mesh devices ("Y"-mesh or sheet mesh) have been sold for POP repair for years, and in fact, Dr. Garely has implanted these products using the sacrocolpopexy procedure – the recognized gold standard for POP repair – for years, and he continues to do so. (*See, e.g.*, Garely depo., 48:3-49:16; 53:21-63:19). Defendants' challenge to Dr. Garely's safer alternative design opinions are factually baseless, and its motion should be denied.

CONCLUSION

Dr. Garely is well-qualified and his opinions are reliable. The Court should reject Defendants' challenges to Dr. Garely's opinions discussed above, and their motion to exclude Dr. Garely's opinions should be denied.

This 13th day of May, 2016.

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from PRONOVA blend materials"; ETH.MESH.03722384 (9/16/09 internal e-mail) Dr. Thomas Divilio: "We're seeing a lot of work published that indicates that polypropylene produces an ongoing, chronic inflammatory reaction…Might be better off working with something that is less reactive, like PVDF"; ETH.MESH.00857704 (2/12/09 internal e-mail regarding future mesh design advantages) – "If we use PRONOVA a more elastic fiber which shows less degradation than PP. Better, longer function of Implant."

CERTIFICATE OF SERVICE

I hereby certify that on May 13, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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